acute myocardial infarction. In addition subjects with B2/C lesions, which are known to have a higher risk for cardiac complications or restenosis have been evaluated.

RESULTS Nine hundred seventy one men (72%) and three hundred eighty five women were enrolled at 43 sites in 14 countries. The mean age was 66.1 ± 10.7, ranging from 29 - 91 years. The majority of subjects presented with hypertension 76%, hypercholesteremia 60%, smoker 55%, and diabetes 30%. 48% of all stented vessels had a diameter ≤2.75mm, 4% presented with chronic total occlusion. Eleven percent of the subjects experienced unstable angina, 47% stable angina. Acute MI was seen in 33% of the subjects (NSTEMI 22%, STEMI 11%). The portion of elderly subjects (≥75 years) is represented by 25%. An unbiased patient population was seen in the registry with more than 52% type B2/C lesions. Moderate and severe calcification was observed in 31%. The Orsiro hybrid stent system demonstrated excellent device (98.7%) and procedure success (98.2%). In this all-comers setting a TLF rate of 5.1% was observed within the first 12 months. The low TLF rate was also confirmed for the subgroups: diabetics (7.7%), acute MI (7.2%), small vessel (5.8%), CTO (1.8%) and complex B2/C lesions (5.1%).

CONCLUSION The results observed in this "real world" population demonstrate a low TLF rate comparable to other state of the art DES at 6- and 12-months.

CRT-156

Two Year Safety And Clinical Performance Of The Drug Eluting Orsiro Stent In The Treatment Of Subjects With Single De Novo Coronary Artery Lesions (BIOFLOW-II)

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OBJECTIVES BIOFLOW-II is a randomized controlled study, comparing the clinical efficacy of the Orsiro Hybrid Drug Eluting Stent (Orsiro) with the Xience Prime™ Everolimus Eluting Stent (Xience Prime) at 2 Years in the complete study population as well as in the diabetic and small vessel subgroups, which are known to have a higher risk for cardiac complications. Here we present the outcome through the clinical endpoints Target Lesion Failure (TLF) and Stent Thrombosis (ST).

METHODS A total of N=452 subjects (62.7±10.4, 38-80 yrs) were enrolled in the Intention to Treat population in the BIOFLOW-II study, registered at clinicaltrials.gov (NCT01356888). All subjects were stratified for diabetes and then randomly assigned (2:1) to receive the Orsiro or the Xience Prime stent. The diabetic subgroup accounted for 28.3% N=128 (Orsiro N=84, Xience Prime N=44) of all subjects. The small vessel cohort included all subjects with a reference vessel diameter ≤2.75mm, accounting for 57.3% N=259 (Orsiro N=168, Xience Prime N=91) of all subjects. Clinical follow up visits are performed at 1, 6, 12 months and annually up to 5 years after the procedure. All angiographic images were analyzed by an independent Corelab. All clinical events were adjudicated by an independent clinical events committee.

RESULTS All three study groups showed comparable populations in both randomization arms in terms of demographics, current risk factors, clinical history and lesion/vessel characteristics. The TLF rate at 24 months was 8.4% for the Orsiro vs. 10.0% for the Xience Prime in the full cohort, 9.7%vs. 9.1% in the diabetic subgroup and 9.4% vs. 13.3% for subjects with small vessel lesions. There was no statistical significance between the two study arms in any of the three analyzed populations. No ST (definitive, probable or possible) occurred through 24 months in the Orsiro arm. Conclusion In this RCT the clinical event rates of the Orsiro SES with a biodegradable polymer were low and comparable to the Xience Prime up to 24 month in all three analyzed populations.

CRT-157

Does the Drug Eluting Stent Implantation Decrease with Age Increase in Elderly Population?

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BACKGROUND The aim of this study is to investigate whether age increase affects the decision to use drug-eluting stents (DES) in elderly patients undergoing percutaneous coronary intervention (PCI).

METHODS This is a single center registry including elderly patients (≥ 65 year-old) undergoing PCI. We defined first DES era as the period between April 2003 and July 2008, and second DES era the period of July 2008 to March 2014. Multivariable model was created for both eras to assess the independent factors associated with DES implantation and the impact of age (per 10 year increase).

RESULTS A total of 8,598 elderly patients were included, of whom 4,528 (52.7%) and 4,070 (47.3%) underwent PCI in the first and second generation DES eras, respectively. Multivariable logistic regression showed that age increase of per 10 years was associated with less likelihood to receive DES implantation. Similarly, patients with acute myocardial infarction, chronic renal insufficiency, chronic heart failure, cardiac shock and current smoking were less likely to receive DES in the two DES eras.

CONCLUSION Among elderly patients undergoing PCI, age is independently associated with a lower likelihood of DES implantation in the second generation era. This finding may highlight the clinical difficulty in assessing the risk/benefit balance of DES in the elderly population.

Table I. Adjusted Multivariate Logistic Outcome

Variable	First-generation era		Second-generation era	
	OR [95% CI]	p value	OR [95% CI]	p value
Age (10 years)	0.78(0.69-0.89)	<0.001	0.53(0.47-0.58)	<0.001
African American	0.9(0.75-1.10)	0.303	0.87(0.74-1.02)	0.079
Male	0.82 (0.69-0.98)	0.026	0.93 (0.79-1.08)	0.331
Diabetes	0.96 (0.81-1.15)	0.662	1.27 (1.08-1.48)	0.003
Hypertension	0.63 (0.46-0.85)	0.003	0.86(0.67-1.12)	0.266
AMI	0.36 (0.28-0.46)	< 0.001	0.33(0.26-0.41)	<0.001
Cardiac shock	0.32(0.21-0.49)	<0.001	0.30 (0.19-0.48)	<0.001
CHF	0.75 (0.61-0.91)	0.005	0.78 (0.65-0.94)	0.011
CRI	0.89 (0.72-1.11)	0.301	0.77 (0.65-0.92)	0.004
PVD	1.02 (0.82-1.25)	0.887	1.09 (0.90-1.31)	0.377
PTCA history	1.33 (1.09-1.61)	0.004	1.61(1.35-1.91)	<0.001
CABG history	1.05(0.85-1.29)	0.678	1.01 (0.84-1.21)	0.929

CABG: Coronary artery bypass grafting; CRI: Chronic renal insufficiency; PTCA: Percutaneous transluminal coronary angioplasty; PVD: Peripheral vessel disease; CHF: Congestive heart failure; AMI: Acute myocardial infarction

CRT-158

Comparison Of Everolimus- And Paclitaxel-eluting Stents in Dialysis Patients

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BACKGROUND We previously reported that the incidence of 1-year major adverse cardiac events (MACE) in patients treated with paclitaxel-eluting stents (PES) was lower than that in the sirolimus-eluting stents, mainly due to reduction of target lesion revascularization (TLR) in dialysis patients. However, it is unclear whether there are differences in clinical outcomes between everolimus-eluting stents (EES) and PES in dialysis patients.

METHODS Between February 2010 and September 2013, 248 maintenance dialysis patients were treated with coronary stents. In this study, 102 maintenance dialysis patients with 135 lesions treated with EES were compared to 107 maintenance dialysis patients with 147 lesions treated with PES. Of these, 60 patients were prospectively randomized to either EES (32 patients) or PES (28 patients) between March 2011 and September 2013. Angiographic and 1-year clinical outcomes were investigated.

RESULTS Diabetes mellitus (DM) was present in 64.7% in the EES group and 71.0% in the PES group (p=0.33). Dialysis period was 6.4 ± 6.3 years vs 6.2 ± 5.9 years respectively (p=0.77). Heavy calcification was in 27.4% vs 34.0% (p=0.23). In-stent restenosis lesion was in 14.1% vs 10.9% (p=0.42). There were no significant differences in reference diameter (2.62 ± 0.64mm vs 2.66 ± 0.60mm, p=0.52) and lesion length (15.0 ± 12.2mm vs 16.5 ± 11.4mm, p=0.29). Rotational atherectomy was undergone in 11.1% vs 23.1% (p<0.01). Total stented length was not significantly different (23.5 ± 14.6mm vs 24.4 ± 13.2mm, p=0.60). One patient in the EES group was lost to follow up. Angiographic follow-up was obtained in 73.3% vs 74.8% (p=0.77). Restenosis rate was not significantly different (18.2% vs 13.6%, p=0.37). At 12 months, MACE occurred in 13.2% in the EES group and 17.4% in the PES group (p=0.25). TLR was observed in 9.5% vs 10.4% respectively (p=0.77). Mortality was 11.8% vs 13.1% (p=0.35). Cardiac death was 5.0% vs 7.7% (p=0.09). Definite stent thrombosis was observed in 2.0% vs 0% (p=0.14). Subgroup analysis in patients with DM revealed no significant differences in MACE (12.7% vs 14.9%, p=0.36), TLR (8.3%